

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Dietary Supplement Subcommittee of the Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dietary Supplement Subcommittee of the Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 25, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn (Ballrooms A and B), 10000 Baltimore Ave., College Park, MD, 301-345-6700.

Contact Person: Constance J. Hardy, Center for Food Safety and Applied Nutrition (HFS-811), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1433, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

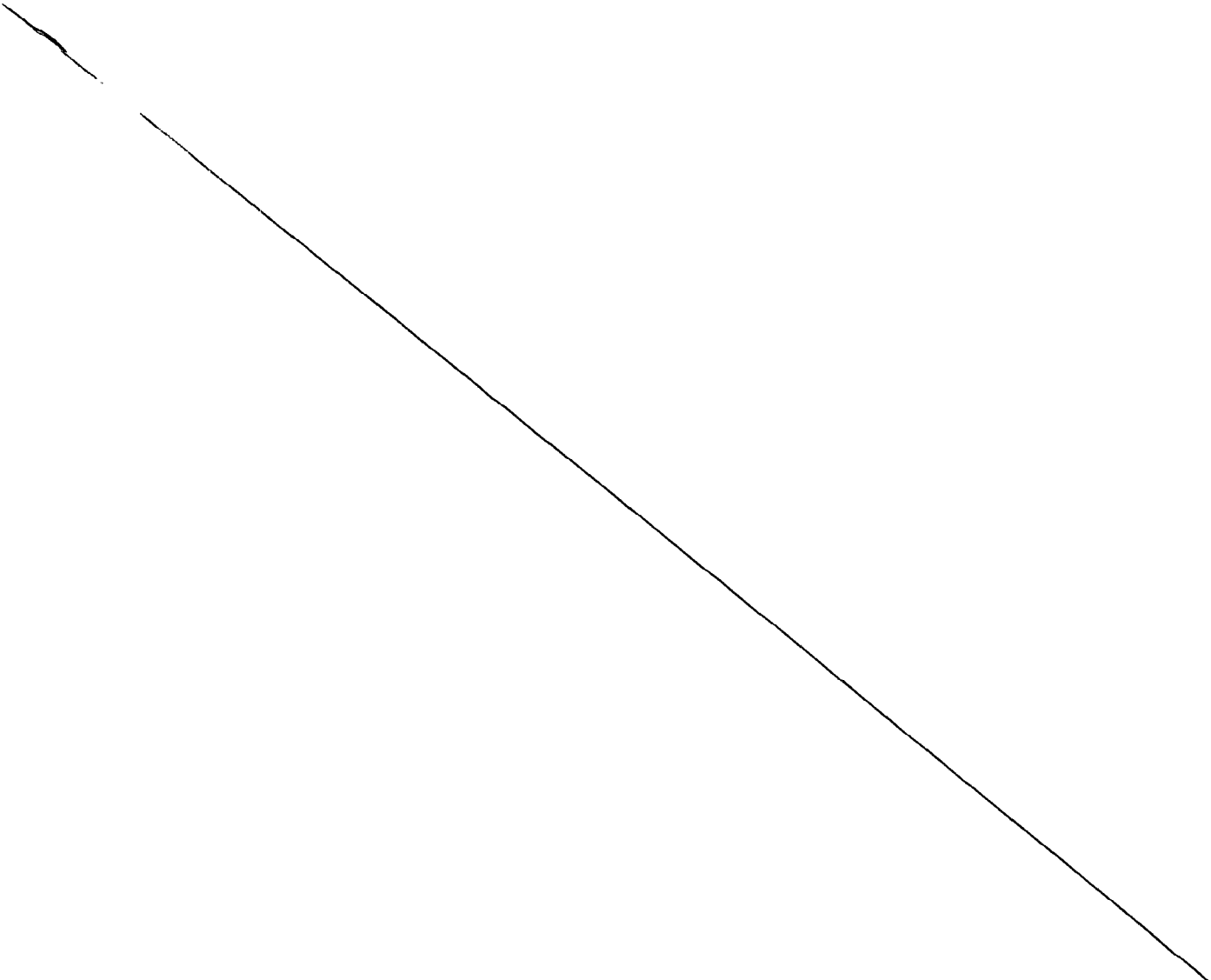
Agenda: To be a dietary supplement as defined in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(ff)), a product must contain at least one “dietary ingredient.” Section 201(ff)(1) of the act lists those substances that are considered “dietary ingredients.” Among other things, the term “dietary ingredient” includes a metabolite of any other dietary ingredient defined in section 201(ff)(1) of the act. The statute is ambiguous, however, as to what substances are, or are not, metabolites of other substances. The practical result of this ambiguity is that it is often difficult to determine whether a particular substance meets the dietary ingredient definition and, therefore, whether products containing the substance can be marketed as dietary supplements. The purpose of this meeting is to explore whether there are recognized scientific principles that would facilitate reaching a conclusion as to whether a particular substance is a “metabolite” of another substance that is a “dietary ingredient” defined in the act and, therefore, is itself a dietary ingredient within the scope of section 201(ff)(1) of the act. The background material for this meeting will be posted on the Internet when available or 1-working day before the meeting at <http://www.cfsan.fda.gov/~lrd/vidtel.html>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 17, 2003. Oral presentations from the public will be scheduled on March 25, 2003, between approximately 11 a.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 20, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names

and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

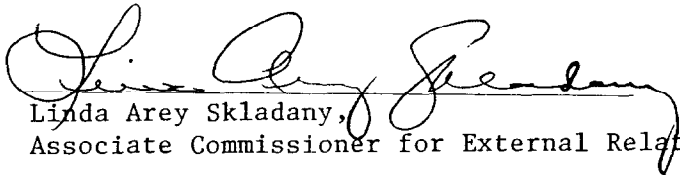
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Constance J. Hardy at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: Feb. 27, 2003
February 27, 2003.


Linda Arey Skladany,
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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